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Canada

Screening Assessment

Talc
($Mg_3H_2(SiO_3)_4$)

Chemical Abstracts Service Registry Number
14807-96-6

Environment and Climate Change Canada
Health Canada

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Synopsis

Pursuant to section 74 of the *Canadian Environmental Protection Act, 1999* (CEPA), the Minister of the Environment and the Minister of Health have conducted a screening assessment of talc. The Chemical Abstracts Service Registry Number (CAS RN[1]) for talc is 14807-96-6. This substance is among those substances identified as priorities for assessment as it met categorization criteria under subsection 73(1) of CEPA.

Talc is a naturally occurring mineral. In 2011, talc was manufactured in Canada in quantities ranging between 50 to 75 million kg, and in 2016, approximately 100 million kg of talc was imported into Canada. In Canada, talc is used in adhesives and sealants; automotive, aircraft, and transportation applications; building and construction materials; ceramics; electrical and electronics; textiles; floor coverings; inks, toners, and colourants; lubricants and greases; oil and natural gas extraction applications; paints and coatings; paper and paper products, mixtures, and manufactured items; plastic and rubber materials; toys, playground equipment and sporting equipment; and in water treatment. The major uses in Canada align with major global uses of talc. Talc is a permitted food additive and is an ingredient in self-care products. In North America, approximately 2% to 4% of the talc produced and sold is used in cosmetics. High-purity talc is used in self-care products including cosmetics, while lower-grade talc is used in commercial applications.

The ecological risk of talc was characterized using the Ecological Risk Classification of Inorganic Substances (ERC-I), which is a risk-based approach that employs multiple metrics for both hazard and exposure, with weighted consideration of multiple lines of evidence for determining risk classification. Hazard characterization in ERC-I included a survey of published predicted no-effect concentrations (PNECs) and water quality guidelines, or the derivation of new PNEC values when required. Exposure profiling in ERC-I considered two approaches: predictive modelling using a generic near-field exposure model for each substance and an analysis of measured concentrations collected by federal and provincial water quality monitoring programs. Modelled and measured predicted environmental concentrations (PECs) were compared to PNECs, and multiple statistical metrics were computed and compared to decision criteria to classify the potential for causing harm to the environment. Based on the outcome of the ERC-I analysis, talc is considered unlikely to be causing ecological harm.

Considering all available lines of evidence presented in this screening assessment, there is a low risk of harm to the environment from talc. It is concluded that talc does not meet the criteria under paragraphs 64(*a*) or (*b*) of CEPA as it is not entering the

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environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends.

Talc has been reviewed internationally by other organizations, including the International Agency for Research on Cancer (IARC) and the Danish Environmental Protection Agency. These assessments informed the human health risk assessment.

No critical health effects were identified via the oral or dermal routes of exposure. As such, oral exposure to talc resulting from food intake and oral and dermal exposure from the use of self-care products are not of concern. Inhalation exposure via ambient air for the general population from industrial and commercial uses of talc was not identified to be of concern for human health given the limited number of sites producing and processing talc in Canada. Rather, the focus of the assessment is on inhalation and perineal exposure to certain self-care products containing cosmetic- or pharmaceutical-grade talc.

With respect to inhalation exposure, non-cancer lung effects (e.g., inflammation, impaired lung function, fibrosis) were identified as a critical health effect for risk characterization on the basis of United States National Toxicology Program studies conducted with rats and mice exposed to cosmetic-grade talc. There is potential for inhalation exposure to talc powder during the use of certain self-care products (e.g., cosmetics, natural health products, non-prescription drugs formulated as loose powders). Self-care products formulated as pressed powders (e.g., face makeup) are not of concern for inhalation exposure. Margins of exposure between air concentrations following the use of dry hair shampoo and foot powder and critical lung effects observed in animal studies are considered adequate to address uncertainties in the health effects and exposure databases. Margins of exposure between air concentrations following the use of body powder, baby powder, and loose face powder and critical lung effect levels observed in animal studies are considered potentially inadequate to address uncertainties in the health effects and exposure databases.

With regards to perineal exposure, analyses of the available human studies in the peer-reviewed literature indicate a consistent and statistically significant positive association between perineal exposure to talc and ovarian cancer. The available data are indicative of a causal effect. Given that there is potential for perineal exposure to talc from the use of certain self-care products (e.g., body powder, baby powder, diaper and rash creams, genital antiperspirants and deodorants, body wipes, bath bombs, bubble bath), a potential concern for human health has been identified.

Considering all the information presented in this screening assessment, it is concluded that talc meets the criteria under paragraph 64(*c*) of CEPA as it is entering or may enter the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

It is therefore concluded that talc meets one of the criteria set out in section 64 of CEPA. It has also been determined that talc meets the persistence criteria but not the bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPA.

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1. Introduction

Pursuant to section 74 of the *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 1999), the Minister of the Environment and the Minister of Health have conducted a screening assessment of talc to determine whether this substance presents or may present a risk to the environment or to human health. This substance was identified as a priority for assessment as it met categorization criteria under subsection 73(1) of CEPA (ECCC, HC [modified 2017]).

The ecological risk of talc was characterized using the Ecological Risk Classification of Inorganic Substances (ERC-I) (ECCC 2018), which is a risk-based approach that employs multiple metrics for both hazard and exposure, with weighted consideration of multiple lines of evidence for determining risk classification. Hazard characterization in ERC-I included a survey of published predicted no-effect concentrations (PNECs) and water quality guidelines, or the derivation of a new PNEC value when required. Exposure profiling in ERC-I considered two approaches: predictive modelling using a generic near-field exposure model for each substance and an analysis of measured concentrations collected by federal and provincial water quality monitoring programs. Modelled and measured predicted environmental concentrations (PECs) were compared to PNECs, and multiple statistical metrics were computed and compared to decision criteria to classify the potential for causing harm to the environment.

With respect to human health, this screening assessment includes the consideration of information on chemical properties, environmental fate, hazards, uses, and exposures, including additional information submitted by stakeholders. Relevant data were identified up to October 2020. Empirical data from key studies, as well as results from models, were used to reach conclusions. Talc has been reviewed internationally through the International Agency for Research on Cancer (IARC) Monographs Programme, the United States Environmental Protection Agency (U.S. EPA), the Joint Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO) Expert Committee on Food Additives (JECFA), and the Danish Environmental Protection Agency (Danish EPA). Talc was also assessed by the Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (MAK-Commission) in Germany and the Cosmetic Ingredient Review (CIR) Expert Panel.[2] These evaluations and reviews were used to inform the health effects characterization in this screening assessment. This assessment focuses on health effects associated with cosmetic- and pharmaceutical-

[2] The Cosmetic Ingredient Review was established in 1976 by the industry trade association (then the Cosmetic, Toiletry, and Fragrance Association, now the Personal Care Products Council), with the support of the U.S. Food and Drug Administration and the Consumer Federation of America.

grade talc and not on potential impurities, such as asbestos. Engineered nanomaterials composed of or containing talc are not explicitly considered in this assessment.

This screening assessment was prepared by staff in the CEPA Risk Assessment Program at Health Canada and Environment and Climate Change Canada and in the Consumer and Hazardous Products Safety Directorate at Health Canada and incorporates input from other programs within these departments. Health Canada scientists conducted research to characterize airborne particles emitted during application of cosmetic talc products (Rasmussen et al. 2019). This peer-reviewed published research has informed the assessment. The ecological portion of the assessment is based on the ERC-I (published May 11, 2018), which was subject to an external peer review and a 60-day public comment period. The human health portion of this assessment has undergone external peer review. Comments on the technical portions relevant to human health were received from T. Lopez, MSPH, K. Super, DABT, and Z. Jeney, MPH, of Tetra Tech. Additionally, the draft of this screening assessment was subject to a 60-day public comment period. Additional information submitted during the public comment period was reviewed and considered for the final screening assessment. While external comments were taken into consideration, the final content and outcome of the screening assessment remain the responsibility of Health Canada and Environment and Climate Change Canada.

This screening assessment focuses on information critical to determining whether substances meet the criteria as set out in section 64 of CEPA by examining scientific information and incorporating a weight of evidence approach and precaution.[3] This screening assessment presents the critical information and considerations on which the conclusion is based.

2. Identity of substance

Talc (CAS RN[4] 14807-96-6) is one of the softest naturally occurring minerals, made up of magnesium, silicon, hydrogen and oxygen (ChemIDplus 1993-). The term talc refers

[3] A determination of whether one or more of the criteria of section 64 of CEPA are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and products available to consumers. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Hazardous Products Regulations*, which are part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion on the basis of the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other acts.

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to both the pure mineral and a wide variety of soft, talc-containing rocks that are mined and used for a variety of applications (Kogel et al. 2006). Relatively pure talc ore is also referred to as steatite, and soapstone refers to impure, massive talc rock (Fiume et al. 2015).

The mineral talc is composed of triple-sheet crystalline units, consisting of two silicate sheets composed of SiO_4 tetrahedra joined by edge-linked $MgO_4(OH)_2$ (Zazenski et al. 1995). These layers, held together loosely via van der Waals forces, slide over one another easily, giving talc its slippery feel and accounting for its softness (Fiume et al. 2015). The size of an individual talc platelet (i.e., a few thousand elementary sheets) can vary from approximately 1 µm to over 100 µm, depending on the conditions of formation of the deposit (EuroTalc 2017). The individual platelet size determines the lamellarity of a sample of talc. Highly lamellar talc will have large individual platelets, whereas microcrystalline talc will have small platelets. Other inorganics in place of magnesium and silicon are common in talc; for example, aluminum and iron may substitute for silicon in the tetrahedral sites, or manganese may substitute for magnesium in the octahedral positions (Zazenski et al. 1995).

Commercially exploited talc contains 20% to 99% of the pure mineral (Kogel et al. 2006). Some of the most common minerals that occur with talc are carbonates (e.g., dolomite, calcite, magnesite) and chlorite (i.e., magnesium aluminum silicate) (CIR 2013). Less common minerals include quartz, mica, iron oxides, pyrite, serpentine, and amphibole. Selective mining, ore processing, and beneficiation can remove many of the impurities (Kogel et al. 2006). There is a trend towards upgrading to higher-purity talc; however, many applications require the properties of the minerals associated with talc (Kogel et al. 2006) and the purity of the source talc influences its uses.

There are different grades of talc that refer to the purity (presence of other minerals). Pharmaceutical-grade talc complies with the United States Pharmacopeia (USP) standards (or similar standards), which require the absence of asbestos and set limits on iron, lead, calcium, and aluminum (USP 2011). As per B.01.045 of the *Food and Drug Regulations*, when used as a food additive, talc must meet the food-grade specifications set out in with the most recent edition of the *Food Chemicals Codex*, published by the United States Pharmacopeial Convention or the *Combined Compendium of Food Additive Specifications*, prepared by the Joint FAO/WHO Expert Committee on Food Additives, and must be free from asbestos (Canada [1978]; FAO 2006; FCC 2016).

Historically, some talc source materials were contaminated with asbestos. However, in 1976, the Cosmetic Toiletry and Fragrance Association (CTFA) set purity standards for cosmetic-grade talc resulting in a reduction in asbestos levels in cosmetic products (Fiume et al. 2015). Cosmetic-grade talc should comply with USP standards that require a limit of 20 ppm lead and an absence of asbestos (Fiume et al. 2015). Currently the USP standard for talc is under review (USP 2019; USP 2020a, USP b) and the United States Food and Drug Administration (U.S. FDA) is working on recommendations on

testing methods for asbestos in talc and products available to consumers containing talc (U.S. FDA 2020a). Internationally, a number of regulatory agencies continue to conduct testing on talc-based cosmetic products for the presence of asbestos (NVWA 2018; U.S. FDA 2020b).

In Canada, the *Prohibition of Asbestos and Products Containing Asbestos Regulations* (updated 2018) under CEPA prohibit asbestos above trace levels in products available to consumers, including cosmetics. The cosmetic-grade talc used in the health effect studies cited in this assessment were considered to be free of asbestos.[5]

Talc is milled to different particle sizes for specific commercial applications. Most talc for cosmetics and pharmaceuticals is pure 200-mesh roller-milled talc (Kogel et al. 2006). In 200-mesh talc (preferred for body powder and deodorants), the particle size distribution allows 95% to 99% of the product to pass through a 200-mesh (74 µm) screen (Zazenski et al. 1995; Kogel et al. 2006). The finer 325-mesh talc is also used in cosmetic-, pharmaceutical-, and food-grade formulations, where 95% to 99% of the product passes through a 325-mesh (44 µm) screen.

3. Physical and chemical properties

A summary of physical and chemical properties of talc is presented in Table 3-1. Talc is a chemically inert, solid powder that is insoluble in water (Kogel et al. 2006, EuroTalc 2017).

Table 3-1. Experimental physical and chemical property values (at standard temperature) for talc

Property	Range	Key reference
Physical state	solid, powder	HSDB 2005
Melting point (°C)	1500	EuroTalc 2017
Vapour pressure (mm Hg)	approx. 0, negligible at 20°C	OSHA 1999; NIOSH 2014
Water solubility (mg/L)	Insoluble	HSDB 2005
Specific gravity (unitless)	2.58–3.83	HSDB 2005

4. Sources and uses

Talc is a naturally occurring mineral, and there are talc deposits in most Canadian provinces (Kogel et al. 2006). Currently, there is one producing mine (open-pit) and

[5] met the USP standards for absence of asbestos

concentrator facility in Canada, in Penhorwood Township near Timmins, Ontario, and one micronizing facility in Timmins (Kogel et al. 2006; MAC 2019; NPRI 2018). The talc ore from the mine is approximately 45% pure, with magnesite, magnetite, chlorite, and serpentine as the major impurities (Kogel et al. 2006). After beneficiation, this mine and micronizing facility produces talc primarily for the paper, plastics, paint, and ceramic sectors (Kogel et al. 2006). In 2019, China was the largest producer of talc, followed by India and Brazil (USGS 2020). The major uses of talc globally include paper, plastics, paint, ceramics, putties, and cosmetics (USGS 2000; Kogel et al. 2006; EuroTalc 2017; USGS 2020).

Talc was included in a survey issued pursuant to a CEPA section 71 notice. Talc was reported to be manufactured in Canada at quantities ranging from 50 to 75 million kg in 2011 (EC 2013).[6] According to the Canadian International Merchandise Trade (CIMT) database, in 2016, 99 549 000 kg of natural steatite and talc, crushed or powdered (Harmonized System, HS code 252620) and 4 656 000 kg of natural steatite and talc, not crushed, not powdered (HS code 252610) were imported into Canada (CIMT 2017).

According to information submitted in response to a CEPA section 71 survey (EC 2013), results from voluntary stakeholder engagement (ECCC, HC 2017), and a search of websites from talc producers, manufactured or imported talc is used in Canada in adhesives and sealants; automotive, aircraft, and transportation applications; building and construction materials (e.g., wood and engineered wood); ceramics; electrical and electronics; textiles; floor coverings; inks, toners, and colourants; lubricants and greases; oil and natural gas extraction applications; paints and coatings; paper and paper products, mixtures, or manufactured items; plastic and rubber materials; toys, playground equipment and sporting equipment; and in water treatment.

Talc is a formulant in pest control products registered in Canada (Health Canada 2010; personal communication, email from the Pest Management Regulatory Agency, Health Canada, to the Risk Management Bureau, Health Canada, dated March 29, 2017; unreferenced).

Additionally, in Canada talc is on the *List of Permitted Food Additives with Other Accepted Uses* (List 8) for limited uses in a small number of foods (Health Canada [modified 2020]). Talc can be used as a coating agent on dried legumes and rice and as a filler and dusting powder for chewing gum as per the *List of Permitted Food Additives with Other Accepted Uses*, incorporated by reference into its respective Marketing Authorization issued under the *Food and Drugs Act*. It may be used as a component in

[6] Values reflect quantities reported in response to the survey conducted under section 71 of CEPA (EC 2013). See survey for specific inclusions and exclusions (schedules 2 and 3).